

INTEGRATING TECHNOLOGY TO SUPPORT AND MAINTAIN GLYCEMIC CONTROL
IN PEOPLE WITH DIABETES

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INTEGRATING TECHNOLOGY TO SUPPORT AND MAINTAIN GLYCEMIC CONTROL
IN PEOPLE WITH DIABETES

A
PROJECT

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By

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Abstract

Type II diabetes is a chronic disease state that leads to increased morbidity and mortality and impacts the lives of millions of Americans. This quality improvement project explored the use of a free smartphone application, *Glucose Buddy*, in aiding people with Type II diabetes to achieve and maintain glycemic control. The project was conducted through the involvement of patients at the Creekside Family Health Clinic in Ketchikan, Alaska over a three month time period. Pre-intervention hemoglobin A1c (HA1c) was compared with post-intervention HA1c. The project, due to the small sample size and high withdraw rate, was not statistically significant. However, there was clinical significance as it showed a decrease in HA1c levels in 60% of the participants.

The Integration of Technology to Support and Maintain Diabetes Control

Type II diabetes is a chronic metabolic disease state that is characterized by hyperglycemia as a result of cellular resistance to insulin action and a deficiency in the secretory response to insulin (ADA, 2014). The criteria for diagnosis includes: a fasting plasma glucose at or greater than 126mg/dL, a 2 hour plasma glucose at or greater than 200 mg/dL during an oral glucose tolerance test, an H_{A1c} at or greater than 6.5%, or a random plasma glucose of at or greater than 200 mg/dL in a person with symptoms of hyperglycemia or hyperglycemic crisis (ADA, 2016). The ADA (2016) has recommended a confirmatory test in the absence of the classic symptoms of hyperglycemia (polyuria, polydipsia, nocturia, blurred vision, and weight loss). Approximately 24 million Americans currently have diabetes and 57 million American adults have pre-diabetes (Center for Disease Control [CDC], 2009). This disease is the leading cause of kidney failure, lower extremity amputations, and blindness in individuals age 20 to 74 (CDC, 2009). If current trends in diabetes continue 33% of Americans born in the year 2000 will develop diabetes in their lifetime (CDC, 2009).

The causal agent of Type II diabetes is believed to be multifactorial, with age, obesity, and a sedentary lifestyle as known risk factors (ADA, 2014). This chronic disease is expensive to treat and control. In the United States, approximately \$245 billion—\$176 billion in direct medical cost and \$69 billion in workforce reduction—was spent on diagnosed diabetes in 2012 (ADA, 2013). This is an average of \$13,700 per individual diagnosed in 2012 representing a 41% increase from the \$174 billion spent in 2007.

Preventative measures have produced a 21% reduction in diabetes related end stage renal disease and an 18% reduction in diabetes related visual impairment (CDC, 2009). The majority of preventative measures have focused on lifestyle changes that include physical activity and

nutritional modification (Baker et al., 2011). In a systematic review of randomized controlled trials, Baker et al. (2011) showed lifestyle changes, nutritional changes, and physical activity were all effective in preventing or delaying the onset of Type II diabetes. They argued the integral component for success in treating and preventing diabetes was the addition of a strong behavioral modification component. The studies reviewed were performed by a variety of providers including registered dietitians, medical doctors, nurses, physician assistants, nurse practitioners, and therapists. Clinicians employed a comprehensive individualized delivery system, frequent personal contact, and numerous contact hours. Baker et al. (2011) questions if similar efficacy could be provided through remote contact in an attempt to provide a more cost-effective approach.

The ADA *Standards of Medical Care in Diabetes* (2015) recommend the following as the best practices for management of diabetes: behavioral modifications, physical exercise, nutritional modification, medication compliance, monitoring blood glucose, and the reduction of cardiovascular risks. The ADA *National Standards for Diabetes Self-management Education and Support* recommends monitoring blood glucose according to healthcare provider recommendations and using the results to guide decision making (Haas et al., 2012). Patients should be educated to prevent, detect, and treat acute and chronic complications associated with diabetes. Additionally, patients should incorporate nutritional management and physical activity in their lifestyles and they should create strategies to promote health and behavioral changes. Self-monitoring blood glucose, dietary, and exercise recommendations widely vary as they require individualization. Daily use of this program will create positive behavioral changes that align with the recommendations of the ADA.

The ADA (2016) recommends healthcare providers use self-monitored blood glucose and routine A1c in determining the effectiveness of glucose management. HA1c reflects the amount of glucose that is irreversibly attached to an erythrocyte over its 120 day lifespan (McCulloch, 2014). HA1c has been shown to have a strong predictive value for complications in diabetes (ADA, 2016). The target HA1c level for non-pregnant, adult patients with Type II diabetes is less than 7%. The Kumamoto Study and UK Prospective Diabetes Study established that maintaining a HA1c level less than 7% has demonstrated a significant reduction in retinopathy, kidney disease, macrovascular disease, and neuropathic complications (as cited in ADA, 2016).

The *Glucose Buddy* application provides a tool that helps the patient with diabetes take an active role in managing their care. This application was rated as 4.5 out of 5 stars by 1833 individual reviewers on iTunes (2016). In an overview of 10 smartphone-based glucose monitors, *Glucose Buddy*, was graded as easy to use, free, and noted for its distinct reminder features (Tran, Tran, & White, 2012). Tracking logs provided by *Glucose Buddy* provide an efficient, individualized, and visual way to monitor physical exercise, medication use, lipid levels, blood pressure, nutritional intake, and blood glucose. The tracking logs can be fully customized to the user's preference and include options to allow the individual to view glucose averages during different times of the day and provides an estimation of HA1c. The logs allow the user to overlay the use of medication and exercise on the glucose charts which allows the user to visualize how this impacts their blood glucose. The logbooks are accessible and transferable through email, enabling a more streamlined office visit as well as closer surveillance by the individual's providers. The *Glucose Buddy* application provides reminder notifications if the user has not completed a selected task. *Glucose Buddy* provides a means to create and

support lifestyle changes and assists the user in becoming an active participant in fulfilling the national standards for diabetes self-management.

Technological advances may improve the delivery of cost-effective, evidence-based care by empowering individuals to track target risk factors for organ damage with readily accessible tools. The pairing of technology with behavioral adaptation will empower the individual with diabetes to proactively monitor and maintain target blood glucose levels. This type of empowerment could be responsible for long term changes necessary in preventing the sequela associated with this disease state. The purpose of this project was to determine if *Glucose Buddy* was effective in reducing H_{A1c} levels in patients with Type II diabetes.

Literature Review and Synthesis

The bibliographical databases of PubMed, Cumulative Index to Nursing and Allied Health Literature, and Google Scholar were used to review and synthesize the most current information available pertaining to diabetes and smartphone applications. The search key phrases were ‘diabetes and technology’, ‘diabetes and application’, ‘diabetes and mobile phone’, and ‘diabetes and cellular phone’. The search was limited to peer reviewed articles that were available in English. Four quantitative studies were selected based on the criteria that examined participant use of a smartphone application, telephone, or computer in the surveillance of diabetic health factors. These studies were used to represent the current body of knowledge available on this subject.

Holbrook et al. (2009) performed a randomized trial to investigate the impact of electronic, web-based diabetes support on patients with Type II diabetes in community-based primary care. The study selected 46 providers and 511 patients. The patients were randomly selected with the following inclusion criteria: above the age of 18, diagnosed with Type II

diabetes, fluent in English, and able to understand the instructions of the study. Approximately 40% of the patients were placed in the control group and 60% in the experiment group. The intervention group was instructed to use the Web-based diabetes tracker of the Computerization of Medical Practices for the Enhancement of Therapeutic Effectiveness study II. The Web-based diabetes tracker is an electronic tracker that fully interfaces with the electronic health record of the patient's provider. It was combined with automated telephone reminders and a color-coded tracker page that was mailed to the patients. The telephone reminder calls were provided on a monthly basis and consisted of reminders for medications, laboratory tests, and provider visits. This allowed the patient and the provider to sequentially monitor blood pressure, physical exercise, HA1c, BMI, serum LDL, foot exams, smoking cessation, and albuminuria. These measures were selected as they are recommendations of the Canadian Diabetes Association and the ADA. The control group was instructed to continue their regular diabetic care with their healthcare provider. The primary outcome was calculated as a composite score of the quality of monitoring of HA1c, blood pressure, LDL cholesterol, body mass index, albuminuria, foot exams, smoking cessation, and physical activity. Results were collected 6 months post-baseline scores and resulted in a statistically significant improvement in the monitoring of the intervention group (1.33 v. 0.06). There was also an increase in the number of visits to the primary care provider, as recommended, by the intervention group. There was no statistically significant change in the control group. Limitations of the study consisted of the short length of the study and the lack of post-study follow up. This study showed that the use of electronic monitoring can improve diabetic health factors.

Chang et al. (2007) performed a retrospective pre-and-post cohort study on the impact of telehealth and telephone interventions on blood sugar control in patients with both Type I and

Type II diabetes. Participants who chose the telehealth interventions were provided a touch-screen monitor to enter their symptoms, blood glucose levels, self-management, and provided access to diabetes education portals. Participants who chose the telephonic intervention used a telephone as the means of communicating blood glucose levels and symptoms of diabetes. The study used 259 participants separated into telehealth and telephone intervention groups according to their preference. The participants were patients of the Veterans Administration Hospital with a median age of 55. Caucasians represented 73.3% of the sample, and the baseline HA1c was 9.9 % in the telehealth group and 9.8% in the telephone group. The telehealth intervention resulted in a 2.3% decrease in HA1c and the telephone intervention led to a 2.4% reduction. This nurse practitioner-led study demonstrated the use of either of these interventions to produce a statistically significant reduction in HA1c. The post cohort study was carried out on 192 of the participants, one year after the completion of the study. This study was performed on the previously listed cohorts after the interventions had been discontinued. The post cohort study demonstrated a statistically significant increase in HA1c with the telehealth cohort demonstrating an increase of 1.6% ($SD = 2.0$; $p < 0.01$) and the telephone cohort demonstrating an increase of 0.7% ($SD = 1.81$; $p < 0.01$). Neither cohort's HA1c returned to or rose higher than their baseline scores. This study demonstrated the use of a technological or telephonic component for tracking and providing diabetic support could decrease an individual's HA1c.

Kirwan, Vandelanotte, Fenning, and Duncan (2013) performed a randomized, controlled trial to study the effectiveness of a free smartphone application combined with text messaging feedback on diabetes related outcomes in people with Type I diabetes. In the study, 72 patients were recruited from an online diabetes support group. The participants consisted of 28 males and 44 females with a mean age of 35.2 years. The mean HA1c was 9.08%. Participants from

the study were randomly assigned to a treatment and a control group. Individuals in both groups were instructed to continue their usual diabetes health care with their current practitioner. This consisted of meeting with their healthcare practitioner every three months. This was the extent of the instruction provided to the control group. Participants in the treatment group were instructed to download the iTunes application *Glucose Buddy*. The application is free through iTunes for use on smart devices and computers. *Glucose Buddy* provides an interface that allows users to enter blood glucose levels, insulin dosages, other medications, physical activities, and dietary intake. It enables the user to view these data entries on a customizable graph as well as export the entered data through email (Kirwan et al., 2013). Participants were instructed to log diabetes parameters on the *Glucose Buddy* website but were not given a minimum amount of logging requirements. The information gathered was reviewed by a certified diabetes educator on a weekly basis. Each patient in the intervention was sent a minimum of one text-message per week for six months. These text message consisted of either feedback on logs, diabetes questions, educational tips, or positive reinforcement. All measurements were collected every three months for a total of nine months. The results from the study displayed a statistically significant reduction in H_{A1c} from 9.08% to 7.80% (mean -1.10, *SD* = 0.74, *P* < .001) in the intervention group (Kirwan et al., 2013). A secondary intervention group using only *Glucose Buddy* or text messaging was not implemented in this project and therefore separating the effect was not possible. The study demonstrated the use of *Glucose Buddy* combined with text messaging can decrease H_{A1c} levels.

A meta-analysis of 22 trials consisting of 1657 participants demonstrated the ability of mobile phone interventions for glycemic control in patients with Type I and Type II diabetes (Liang et al., 2010). Most studies employed the use of a short message service (text messaging)

to deliver information to participants. The mean age of the participants was 44 years. The meta-analysis revealed an overall decrease in HA1c values (SMD 0.51%, 95% CI 0.33 to 0.69%) in the treatment groups. A subgroup comparison between patients with Type I and Type II diabetes showed a significantly greater reduction in HA1c values in the individuals with Type II diabetes. The meta-analysis was believed to be the first of its kind in reference to diabetic glycemic control and mobile phone interventions (Liang et al., 2010).

Problem Statement

Diabetes is a complex disease process that is frequently encountered in the primary care setting. Treatment focuses on behavioral modifications that are time intensive, costly, and can be difficult to manage and maintain.

Research Question

What is the effect of the use of Glucose Buddy on HA1c levels in persons with Type II diabetes over a three month period?

Methodology

Participants

The quality improvement project was conducted through the involvement of patients diagnosed with Type II diabetes who use Creekside Family Health Clinic for their primary healthcare needs. This clinic provides primary care to approximately 200 patients diagnosed with Type II diabetes. There was a mixture of patients with long-standing and newly diagnosed Type II diabetes. The services offered by this clinic include primary healthcare, health screening, foot care services, immunizations, and point of care laboratory services.

The sample was generated by the Medical Director at the Creekside Clinic using the clinic's electronic health program with the search term, "diabetes". This generated list was then

placed on an Excel spreadsheet and narrowed to include only individuals with Type II diabetes. This resulted in 123 possible participants. Thirty-five individuals were then selected by the medical director who deemed that they met the inclusion and exclusion criteria of the project and would benefit from the use of a smart phone application to track their diabetes. These individuals were then called by the researcher using the phone transcript provided in Appendix B.

Inclusion Criteria

Participants must use Creekside Family Health Clinic for their primary care services. They must be residents of Ketchikan, Alaska, over the age of 18 years, and diagnosed with Type II diabetes. They must have a glucometer and be willing to check their blood glucose levels as directed by their provider. They must have a smartphone device that is capable of downloading and running the *Glucose Buddy* application.

Exclusion Criteria

Prospective participants were excluded if they were not 18 years of age or older and if they had not been directed by their healthcare provider to regularly check their blood glucose levels. Individuals had to have access to a smart phone, tablet, or other device that supports the Glucose Buddy application. Individuals who do not possess the technical and motor skills appropriate to use this smart phone application were excluded from participation in the project. Individuals who were unable to use smartphone devices due to visual impairments were excluded. Individuals who were unable to come to the Creekside Family Health Clinic for instruction on the use of Glucose Buddy were excluded.

Data Collection Measures and Analysis

Participants were required to download the iTunes/Android application, *Glucose Buddy* version 3.7.0 (see Appendix E for screen shots of the application). Information about the proper use of

Glucose Buddy was presented individually, at the Creekside Family Health Clinic, using the tutorial provided by the *Glucose Buddy* application designer. The participants were asked to demonstrate the technical and motor skills appropriate to use this smart phone application by adding sample glucose measurements into a sample database in their personal smartphone or the researcher's smartphone.

Participants were asked to use this smartphone application to track self-monitored glucose, medications, diet, physical activity, and HA1c for the three months of the research project. The most recent HA1c, prior to the intervention was used as the participant's baseline HA1c lab and the first HA1c at the conclusion of the project constituted the final HA1c level for this research. Results from the baseline and final HA1c and basic demographic data were provided to the researcher, devoid of any identifying information, by the medical director. Due to the lack of normal distribution, the results of the pre and post intervention HA1c scores were analyzed through the use of a Wilcoxon signed-ranks test with SPSS software. Participants were encouraged to continue their usual diabetes healthcare.

Protection of Human Subjects

The participants were informed of the voluntary nature of the project and were allowed to stop their participation at any time (Appendix A). There are no anticipated risks with participation other than those that might occur in day-to-day life. Putting information into a smart phone application and emailing it is not linked with any higher risks than writing them on paper with a pencil. Using this application while driving is dangerous and should not be done.

Participants were guaranteed confidentiality during this project. Digital information that was used during analysis was kept on a password protected computer and deleted at the completion of the project. Storing information on a smartphone comes with certain amount risks

that can be minimized by using a lock screen passcode. This risk is not increased by using the application. Ethical considerations concerning research misconduct, the protection of human subjects, conflicts of interest, data management practices, and the reporting of research were processed through the University of Alaska Anchorage's Institutional Review Board.

Results

Of the initial 12 participants, five completed the project. The mean age of the participants was 53 years (SD 9.3) (2 males, 3 females). The mean length of time since the diagnosis of Type II diabetes was 10.80 years (SD 7.84). The mean time since the last HA1c was 2.60 months (SD 1.81). Descriptive statistics are provided in Appendix C table 3. Because the data were not normally distributed, a Wilcoxon Signed-Ranks test was run and the output indicated that post-analysis HA1c scores were not statistically significant from baseline HA1c scores, $Z = -.944$, $p = .345$, Appendix C table 2. The mean baseline HA1c (mean 9.10%, SD 2.19) compared to the post-analysis HA1c (mean 7.98%, SD 1.36) demonstrates a decrease in HA1c after the intervention as shown in Appendix C table 1.

Limitations

There are limitations to this project that should be noted. The sample size was small and underpowered which limits the ability to detect the effects of the application on HA1c levels. The sample was taken from participants who lived in Ketchikan, Alaska and were members of the Creekside clinic, this did not allow for an accurate profiling of multiple demographics. This sample was not randomly selected; the participants were chosen by the medical director at the Creekside clinic. HA1c levels were not sampled at the initiation of the project, instead the previous HA1c level was used. Usage of the *Glucose Buddy* application was not tracked. Prudence should be advised when generalizing these findings to other patient populations.

Conclusions

This project, due to the small sample size, is not statistically significant. However, there is clinical significance as it showed a decrease in H_{A1c} in 60% of the participants. It is difficult to ascertain the source for the decrease in H_{A1c} with the small sample size of the project. It would be imprudent to attribute this decrease solely to the use of the application without considering other probable causes. Larger studies over longer durations are needed to validate the use of *Glucose Buddy* for patients with type II diabetes. Future studies should aim at increasing the sample size, random selection of participants, increasing the heterogeneity of the sample, frequency of use monitoring, and requiring baseline H_{A1c} at the initiation of the trial.

Outcomes

This quality improvement project was undertaken at the behest of the Creekside Family Health Clinic to examine the use of *Glucose Buddy* as a tool for the management of blood glucose in patients with Type II diabetes. It demonstrated clinical significance through the reduction of H_{A1c} levels in 60% of the participants and will be recommended as an adjunct to ADA guidelines. Future quality improvement projects at Creekside Family Health Clinic should focus on the recruitment of patients during face to face interviews, a longer window for the recruitment process, and inclusion of all patients with Type II diabetes. Initial participation in this study demonstrated interest in 34% of the sample provided by the medical director. The project suffered from a large withdrawal rate (58%) that affected the ability to demonstrate statistical significance or generalize findings. This withdrawal rate may have been the result of not having contact with the participants for three months by the researcher after the initial interview. Future studies may consider adding an additional component such as text messaging or phone calls to decrease the withdrawal rate. A report of the results will be provided to the

Creekside Family Health Clinic and will help them appreciate the efficacy of the application in improving patient's health outcomes.

Impact on Practice

The use of *Glucose Buddy* in the clinical setting could revolutionize the management of diabetes. If this application is successful in improving glycemic control it could help improve diabetic mortality and morbidity by improving glycemic control, creating beneficial dietary and exercise habits, tracking medication compliance, tracking lipids, HA1c, and blood pressures. Healthcare providers will gain the ability to actively monitor their populations that have diabetes electronically saving both time and money. Tutorials and support groups for the application's use are provided by *Glucose Buddy* creating a user-friendly and time-saving, experience for both the healthcare provider and the patient. *Glucose Buddy* provides a comprehensive package that provides the patient with tools to actively manage their diabetes. This application can provide a faster means of communication between the patient and the provider, allowing a more efficient venue for reaching and achieving mutual and individualized healthcare goals.

Dissemination

The information gained from this project will be submitted to the *Journal of Diabetes Science and Technology*. This journal provides the most appropriate venue for circulating a project on the use of a cell phone application and its implications on diabetes care and management. The Medical Director for the Creekside Family Health Clinic will receive the results of this intervention along with recommendations for practice change. This project will further the current knowledge base in the area of technology and diabetes care as well as provide the groundwork for future research in this rapidly expanding field.

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Appendix A

Consent Form

Principle Investigator:

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University of Alaska Anchorage

(863) 224-2903

Faculty Advisor:

Elizabeth Driscoll, RN, MSN, FNP-C, PhD

Project Chair University of Alaska Anchorage

(907) 786-4594

Description:

We would like you to take part in a quality improvement project to see if *Glucose Buddy*, a smartphone application, affects your Hemoglobin A1C. You are being asked to take part because you are currently diagnosed with Type II diabetes and use Creekside Family Health Clinic for your primary healthcare services. This project is a graduate student research project and is being led by a graduate student. Please read this form carefully and ask any questions you may have before agreeing to take part in this project.

What the project is about: The purpose of this project is to see if *Glucose Buddy* can assist people with diabetes in achieving and keeping good blood sugar control.

What we will ask you to do: If you agree to be in this project, we will teach you how to use *Glucose Buddy*. It will take you about 30 minutes to learn this application. During the project, you will be asked to put blood sugar readings into the *Glucose Buddy* application at home. You will continue your regular diabetes care with your primary care provider and continue your usual

care. At the end of three months, you will email your results to your primary care provider. We will give you instructions on how to do this when you agree to participate. We will compare your Hemoglobin A1c labs from before and after you participate in the project to see if they are different. This will not require any additional blood draws, results from your routine blood draws will be used. If you encounter technical problems using the application, please contact the researcher.

Risks and benefits:

We do not anticipate any risks to you by participating in this project other than those that might occur in day-to-day life. Putting information into a smart phone application and emailing it to your primary care provider is not linked with any higher risks than writing them on pencil and paper and bringing them to your primary care provider. Using this application while driving is dangerous and should not be done.

The benefits to participating in this project may include: the ability to visualize your blood sugars on charts, seeing what the effects of diabetes medications have on your blood sugars, the ease of use of electronically sending your data to the diabetes team, tracking your diet and exercise electronically, and potentially lowering your HA1c.

Compensation: There is no compensation offered for participation in this project.

Privacy: Your answers will be confidential. The records of this project will be kept private.

Research records will be kept on a password locked computer; and only the researchers will have access to the records.

Taking part is voluntary: Taking part in this project is completely voluntary. You are able to withdraw at any time without penalty.

Contact people: If you have any questions about this research, please contact the Principal Investigator at the phone number listed above. If you have any questions about your rights as a research subject, please contact Sharilyn Mumaw, Research Compliance Officer, at (907) 786-1099.

I understand the potential risks and benefits to participating in this project and elect to participate.

Signature: _____

Date: _____

Witness: _____

Date: _____

Appendix B

Telephone Transcript

(Patient telephone number and name provided by clinic director.)

Hello, may I speak with Patients name.

My name is Adam Randall.

I am a nursing student at the University of Alaska Anchorage.

I am doing a research study on the effect of using a cell phone application on blood sugars in individuals with Type II diabetes. The medical director at Creekside clinic gave me your phone number and stated that you might be interested in using a cell phone application to track your blood sugars. We hope that using the application will help you and other patients with type 2 diabetes have better control of your blood sugars. We're hoping to get everyone with diabetes at Creekside clinic to help out in this study.

May I ask you a few questions to see if you qualify to participate?

(If no, thank person for time and end call)

(If yes, continue below)

Do you have a smart phone/device (iphone, ipod, ipad or android)?

Do you have any trouble with your eyesight or ability to use your hands that prevent you from using a smart phone or device like an ipad?

Do you check your blood sugar at home?

(If the person does not meet the screening criteria): Thank you for your time. At this point, we can only include people with a device that you can use the application on. (End call)

(If person meets the screening criteria, continue below)

You appear to meet the criteria for participating in the study. If you agree to participate, we will teach you how to use the application on your device. You can use it to keep track of your blood sugars, medications, exercise and diet. After you have used it for three months, we will compare your H_{A1c}s from before you used it and after to see if it made a difference in your blood sugar control. There is no cost to you, it is a free application. There is also no compensation to you for participating. You won't have any additional blood draws. You can choose to stop your participation at any time. Would you like to participate?

(If no): Thank you for your time, I will not contact you again. (End call)

(If yes): When would be a good time for you to come down to the clinic so that we can get you started? We have a video tutorial for you to watch, and a consent form to review with you. This will take no longer than 30 minutes and you will need to bring your cell phone/device with you.

Do you have any questions for me about any aspect of the study at this time?

(Give my name and contact number so patient can call back with questions)

(If no): Thank you for your time and have a good day. (End call)

Appendix C Statistics

Table C-1 Mean comparison of Pre-intervention HA1c and Post-intervention HA1c

Paired Samples Statistics	Mean	N	Std. Deviation	Std. Error Mean
Pre-HA1c	9.10	5	2.19	.982
Post-HA1c	7.98	5	1.36	.608

Table C-2 Wilcoxon Signed Ranks Test

Post-HA1c – Pre-HA1c	N	Mean Rank	Sum of Ranks
Negative Ranks	3a	3.67	11.00
Positive Ranks	2b	2.00	4.00
Ties	0c		
Total	5		

Wilcoxon Signed Ranks Test

Test Statistics	Post-HA1c – Pre-HA1c
Z	-.944
Asymp. Sig. (2-tailed)	.345

Table C-3 Descriptive Statistics of participants

	N	Minimum	Maximum	Mean	Std. Deviation
Age	5	43.00	63.00	53.00	9.38
Months Since Last HA1c	5	1.00	5.00	2.60	1.81
Years since Diagnosis	5	.02	20.00	10.80	7.84

Appendix D
Protection of Human Subjects

DATE: February 23, 2016

TO: Adam Randall, RN, BSN, FNP-S
FROM: University of Alaska Anchorage IRB

PROJECT TITLE: [825478-5] Integrating Technology to Support and Maintain Glycemic Control in People with Diabetes

SUBMISSION TYPE: Amendment/Modification

ACTION: APPROVED DECISION DATE: February 22, 2016

EXPIRATION DATE: February 21, 2017

REVIEW TYPE: Expedited Review

Your proposal received an expedited review and was granted approval with revisions. Thank you for a copy of these [revisions. Therefore, in keeping with the usual policies and procedures of the UAA

Institutional Review Board, your proposal is judged as fully satisfying the U.S. Department of Health and Human Services requirements for the protection of human research subjects (45 CFR 46 as amended/ revised). This constitutes approval for you to conduct the study.

This approval is in effect for one year. If the study extends beyond the expiration date of this letter, you are required to submit a progress report and to request continuing approval of your project from the Board. At the conclusion of your research, submit the required final report to the IRB. These report forms are available on IRBNet.

Please report promptly proposed changes in the research protocol for IRB review and approval. Also, report to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

On behalf of the Board, I wish to extend my best wishes for success in accomplishing your objectives

Ronald S. Everett, Ph.D.

Chair, Institutional Review Board

Appendix E

